Reference number(s)
5998-A

Jurisdiction Specific Medicare Part B Rolvedon

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Rolvedon	eflapegrastim-xnst

Covered Uses

The indications below are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications

Rolvedon is indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in adult patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with clinically significant incidence of febrile neutropenia.

Compendial Uses

- Stem cell transplantation-related indications
- Prophylaxis for chemotherapy-induced febrile neutropenia in patients with solid tumors
- Hematopoietic acute radiation syndrome
- Hairy cell leukemia, neutropenic fever

All other indications will be assessed on an individual basis. Submissions for indications other than those listed in this criteria should be accompanied by supporting evidence from Medicare approved compendia.

Exclusions

Coverage will not be provided for members with any of the following exclusions:

- Administration of the colony-stimulating factor (CSF) to increase chemotherapy dose intensity except as noted below
- Continuous use of the CSF for myelodysplastic syndromes or Felty's syndrome without infections
- Chemosensitization of myeloid leukemias
- Continued use if no response is seen within 28-42 days
- Administration in members with chronic aplastic anemia

Coverage Criteria

Prevention of Febrile Neutropenia in Cancer Patients Receiving Myelosuppressive Chemotherapy and/or Immunotherapy

Authorization of 6 months may be granted for prevention of febrile neutropenia when the chemotherapeutic agents are covered by Medicare and any of the following criteria are met:

- The requested medication will be used for primary prophylaxis in a member whose risk of febrile neutropenia is 20% or greater based on the chemotherapy regimen
- The requested medication will be used for primary prophylaxis in a member whose risk of febrile neutropenia is greater than or equal to 10% and less than 20% based on the chemotherapy regimen and at least one of the following risk factors for febrile neutropenia are present:
    - Age greater than 65 years
    - Poor performance status
    - Previous episodes of febrile neutropenia
    - History of previous chemotherapy or radiation therapy
    - After completion of combined chemoradiotherapy
    - Bone marrow involvement by tumor producing cytopenias
    - Preexisting neutropenia
    - Poor nutritional status
    - Poor renal function
    - Liver dysfunction (i.e., elevated bilirubin)
    - Presence of open wounds or active infections
    - Recent surgery (within the past 12 weeks)
    - Advanced cancer
    - Other serious comorbidities

- The requested medication will be used as secondary prophylaxis when both of the following conditions are met:
    - The member has documented febrile neutropenia from a prior chemotherapy cycle (for which primary prophylaxis was not received)
    - A reduction in dosage of the chemotherapeutic agent or delay in treatment may compromise disease-free or overall survival or treatment outcome

Other Indications

Authorization of 6 months may be granted for members with any of the following indications:

- Stem cell transplantation-related indications
- Hematopoietic subsyndrome of acute radiation syndrome
- Hairy cell leukemia with neutropenic fever following chemotherapy

Dosage and Administration

Services performed for excessive frequency are not medically necessary. Frequency is considered excessive when services are performed more frequently than generally accepted by peers and the reason for additional services is not justified by documentation. If the member is on a dose dense 14-day chemotherapy cycle, it would be acceptable to administer pegfilgrastim outside of the 14-day before and 24-hour after rule for chemotherapy. CSF will be covered when administered under direct supervision in the office setting. When administered by the member or caregiver, the drug will be considered self-administered and not payable.

References

1. Rolvedon [package insert]. Irvine, CA: Spectrum Pharmaceuticals, Inc.; November 2023.
2. White Cell Colony Stimulating Factors LCD (L37176) Version R15. Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed June 19, 2024.
3. Billing and Coding: White Cell Colony Stimulating Factors (A56748) Version R12. Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed June 19, 2024.
4. The NCCN Drugs & Biologics Compendium® © 2024 National Comprehensive Cancer Network, Inc. Available at: https://www.nccn.org. Accessed June 19, 2024.
5. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Hematopoietic Cell Transplantation. Version 1.2024. https://www.nccn.org/professionals/physician_gls/pdf/hct.pdf Accessed June 5, 2024.

6. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Hairy Cell Leukemia. Version 2.2024. https://www.nccn.org/professionals/physician_gls/pdf/hairy_cell.pdf Accessed June 5, 2024.

